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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,727	09/26/2005	Jochen Wonschik	3968.150	8867

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EXAMINER	
MERCIER, MELISSA S	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,727	WONSCHIK ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/7/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

The Office Action dated July 18, 2007 has been vacated. This office action replaced the action of July 18, 2007. Applicant's statutory period of response has been reset with the mailing of this action.

Applicants' arguments, filed May 11, 2007, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-6, 11-12, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603).

Stapler discloses, "microcapsules which contain breath control actives/antimicrobials in the core of the microcapsule along with an organic diluent as well as in the shell of the microcapsule" (column 1 line 65 to column 2, line 2).

Additionally, "the shell material of the microcapsules can be any materials which are suitable for ingestion as well as retention in the oral cavity, including gelatin, polyvinyl alcohols, waxes, gums, sucrose esters and sugar candy type materials used in

cough drops and mints" (column 2, lines 11-16). The thickness of the shell is discloses in the range of 30um to 2mm (column 2, lines 19-20). The particle diameter is in the range of about 2mm to about 9mm (column 2, lines 23-25). Therefore the ratio of thickness of the shell to particle diameter would fall within the claimed values of 0.004 to 0.04:1.

Stapler further discloses, "flavoring agents such as thymol, eucalyptol, menthol, methyl salicylate or witch hazel. These agents are used in an amount of from about 0.1% to about 25%" (column 3, lines 60-65).

Stapler does not disclose the microcapsules being coated or gel points of the gelatin and plasticizer.

Rowe discloses, "a coated capsules comprising a gelatin shell with a flavored coating. A sugar or sugar substitute is included in the material of the shell and that of the coating to stabilize both compositions and the junction there between" (abstract).

Additionally, "the sugar or sugar substitute can include a variety of sugar alcohols or non-reducing saccharides, including sorbitol; polyglycerol; mannitol; xylitol; maltitol; isomalt; and corn syrup (column 3, lines 3-10). Rowe discloses, "the finished capsule shell formulation comprises 65-70% gelatin, 22-25% glycerin, and 8-10% water" (abstract). According to Rowe, the amount of gelatin, water, and plasticizers, such as glycerine preserve a degree of softness and flexibility of the shell (column 1, lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the percentage of each in order to make a capsule with the properties desired. Additionally, it would be obvious to one of ordinary

skill in the art to modify the percentage of plasticizer and the type of plasticizer in order to obtain a specific gel point. It would be within the knowledge of the person of ordinary skill in the art at the time the invention was made to do so in order to obtain a shell with the desired properties of hardness and strength. It is the examiners position that a gel point is a property, which can be modified in order to obtain a capsule with the desired properties and qualities.

Additionally, Rowe discloses, "it is desirable to minimize the quantity of shell material in the coated product, and in this respect it is recognized that with a sufficiently stable interface and bond between the coating and shell, the coating will serve to reinforce the shell, and the shell to effectively seal the coating. Thus, if the shell thickness can be reduced such that its entire thickness is effectively bonded to the coating, then the resultant product will include a bare minimum of shell material" (column 3, lines 38-35). Therefore, it is the examiners position that if it were desirable to keep the shell to a minimum as disclosed by Rowe, the diameter of coated capsules would be similar to those disclosed by Stapler. Additionally, it is also the examiners position that since the purpose to the coating is to reinforce the shell, it would be within the knowledge of one of ordinary skill in this art at the time the invention was made to modify the coating layers and thickness in order to make a stable product.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicants believe that the rejection is a result of inadmissible hindsight reconstruction from a nonanalogous art and there would be no motivation to rely on Stapler to make

the claimed coated microcapsule. A person of ordinary skill in the art would not have consulted documents relating to uncoated microcapsules when trying to develop a coated microcapsule, this is reinforced by the fact that the cited documents are drawn solely to uncoated microcapsules production or solely to coated microcapsule production. The examiner disagrees. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that Stapler is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Stapler discloses Stapler discloses, "microcapsules which contain breath control actives/antimicrobials in the core of the microcapsule along with an organic diluent as well as in the shell of the microcapsule" (column 1 line 65 to column 2, line 2).

Additionally, "the shell material of the microcapsules can be any materials which are suitable for ingestion as well as retention in the oral cavity, including gelatin. While

the Stapler reference does not teach a coating on the shell, it would have be4n obvious to a person of ordinary skill in the art at the time the invention was made to have looked to Rowe who discloses, "it is desirable to minimize the quantity of shell material in the coated product, and in this respect it is recognized that with a sufficiently stable interface and bond between the coating and shell, the coating will serve to reinforce the shell, and the shell to effectively seal the coating. Thus, if the shell thickness can be reduced such that its entire thickness is effectively bonded to the coating, then the resultant product will include a bare minimum of shell material" (column 3, lines 38-35). Therefore, it is the examiners position that if it were desirable to keep the shell to a minimum as disclosed by Rowe, the diameter of coated capsules would be similar to those disclosed by Stapler. Additionally, it is also the examiners position that since the purpose to the coating is to reinforce the shell, it would be within the knowledge of one of ordinary skill in this art at the time the invention was made to modify the coating layers and thickness in order to make a stable product.

Claims 2-4, 7-8, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Matthews et al. (US Patent 4,816,259).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose an intermediate layer of coating or the Bloom value of the gelatin used.

Matthews discloses, soft gels comprising "a gelatin mass that produces a smooth completely dispersed gelatin suspension. The gelatin required for this dispersion should be between 130 bloom and 200 bloom alkali based skin or bone type" (column 2, lines 36-30). Matthew's examples further disclose an enteric-coated soft gelatin capsule made from a gelatin with a bloom value of 150, and a hard gelatin capsule made from a gelatin with a high bloom value. Therefore, it is the position of the examiner that like the gel point, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected of a gelatin with a specific bloom value in order to obtain the desired rigidity of the capsule shell.

Additionally, Matthew's discloses, "after the capsules are air dried, any one of several known coating solutions may optionally be applied to the capsule shell to improve its surface appearance or to render the capsule moisture proof. For example, a coating of confectioners glaze (food grade shellac) dissolved in alcohol may be applied in an amount sufficient to completely cover all surfaces of the capsules. About one to three applications of glaze are usually sufficient to insure adequate dryness, but more or less may be applied. The capsules are again air dried to remove the alcohol solvent (column 2, lines 45-55).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Matthew's with the capsules taught by Stapler and Rowe in order to make capsules which can be used as enteric coated capsules. Additionally Matthew's discloses that such capsules "exhibit an

improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures" (column 1, lines 63-67).

A person of ordinary skill in the art would have a reasonable expectation of success in making the capsules since Stapler, Rowe and Matthews all teach similar capsules as those of the instant claims, with the same intended function.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues for a skilled person not relying on hindsight, Matthews would have only disclosed a shell material composition has to be maintained when in combination with a specific sub coating and if the skilled person would have tried to produce hard gelatin microcapsules based on the Matthews reference they would have been instructed by this reference to increase the sugar content of the shell material. Thus, it would not have been obvious to provide high gelatin content or increase the gelatin content. It is unclear to the examiner what part of the reference would instruct one of ordinary skill to increase the sugar content of the coating in order to make a hard gelatin capsule. Matthews teaches the hard gelatin capsules are prepared using a high bloom gelatin. It is the examiners understand that the higher the bloom number, the stiffer the gelatin, therefore, in order to make a "stiffer" capsule, one of ordinary skill would select a gelatin with a higher bloom number and increase the percentage of gelatin in the composition, not the sugar content.

Claims 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Alamian et al. (US Patent 6,770,311).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose a source of the gelatin used.

Alamian discloses, "granules having a shell with a gelled center, derived from an aqueous mixture containing food grade encapsulation materials, such as water-soluble carregeenans or gelatin. The mixture is introduced in the form of droplets into food grade oil, the temperature of which, at least in its lower layers, is below the temperature at which the droplets congeal to form granules. The thus-formed granules have an outside shell" (column 1, line 57 through column 2, line 5).

Additionally, Alamian discloses, "the food grade encapsulation materials must be able to form a shell, such as gelatin, beef gelatin, fish gelatin, pork gelatin, alginates, and gellan gum" (column 2, lines 34-52).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Stapler and Rowe with the teachings of Alamian since the encapsulation material must have the ability to form a shell or membrane, be stable at temperatures between –10C to 80C and must be light. It would be within the knowledge of one of ordinary skill in the art to select a gelatin, which would create a shell with the qualities desired. Additionally, it is the examiners position that each type of gelatin would have different bloom values and different gel

points, therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have selected the gelatin to best fit the qualities to be obtained.

A person of ordinary skill in the art would have a reasonable expectation of success in making the claimed capsules since all cited references teach capsules with a gelatin shell.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has not provided any additional arguments over those already discussed above.

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Greenberg (US Patent 5,378,131).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose the use of thaumatin, neohesperidine, or miraculin as sweeteners.

Greenberg discloses a chewing gum comprising sweeteners, including sucralose, aspartame, salts of acesulfame, thaumatin, and saccharine and its salts (column 6, lines 1-5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Stapler and Rowe with the sweeteners taught by Greenberg, since Greenberg discloses, "in order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate the artificial sweetener" (column 6, lines 6-9).

One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success since Stapler and Rowe both disclose the use of a sweetener and Greenberg discloses the use high intensity artificial sweeteners to be encapsulated.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has not provided any additional arguments over those already discussed above. .

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Winston Jr. et al. (US Patent 5,342,626).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose the use of 0.4-3% gellan gums in the shell.

Winston discloses a polymer composition comprising 0.1 to 50% gellan gum to be used as flexible films for encapsulation (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used gellan gum in the shell of the capsules taught by Stapler and Rowe. Winston discloses compositions comprising the gellan gum "have numerous advantages including biodegradability, strength, thermal reversibility, water solubility, and reducing processing time" (column 3, lines 2-6).

A person of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success since the use of gellan gum is well known in the art to be useful as a thickener or gelling agent.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has not provided any additional arguments over those already discussed above. .

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Schlameus et al. (US Patent 4,888,140).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose a method of making the capsules comprising the steps of:

a. pumping the core material and a curable shell simultaneously through a concentric multi-component nozzle so that they drip into a cooling liquid with the formation of a capsule;

b. drying the capsules;

c. coating the dried capsules

Schlameus discloses, "a process for preparing round, fluid filled microcapsules by the simultaneous extrusion, of core and shell material from coaxially aligned and concentric extrusion nozzles into a surrounding carrier fluid moving in the direction of the extrusion wherein a surfactant having affinity with the carrier fluid is added to the carrier fluid" (abstract). The microcapsules are placed into a reservoir holding a cold carrier fluid (column 2, lines 2-4).

Schlameus discloses dry weight yields of the process were discussed (column 2, lines 14-21), which would require the microcapsules were dried.

Schlameus does not disclose the coating of the dried capsules. However, Rowe discloses, "a coating can be applied wet, as in a pan coating process" (column 3,lines 23-24).

It would be obvious to a person of ordinary skill in the art at the time the invention was made to have combined the method of Schlameus with the coating method of Rowe. Schlameus discloses, the capsules produced by his method have increased burst strength and Rowe discloses the pan coating process assists in stabilizing the interface between the coating and shell.

A person of ordinary skill in the art would have a reasonable expectation of success in making the capsule of Stapler and Rowe with the method of Schlameus since the combined teachings disclose a core with a shell and a coating used to stabilize the shell.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has not provided any additional arguments over those already discussed above. .

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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